, 228.1010

UNITED STATES PATENT AND TRADEMARK OFFICE

1615

Re:

Application of:

REIN, Hubert et al.

Serial No.:

09/980,727

Filed:

October 19, 2001

For:

METHOD FOR PRODUCING A WATER

INSOLUBLE AMORPHOUS

OR PARTIALLY AMORPHOUS CONTROLLED

RELEASE MATRIX

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

November 19, 2003

Sir:

In accordance with Applicant's duty of disclosure under 37 C.F.R.§1.56 and the provisions of 37 C.F.R. §§ 1.97 and 1.98, Applicants hereby make of record the references listed on the accompanying Form PTO-1449 (18 pages) for consideration by the Examiner in connection with the examination of the above-identified patent application. Pursuant to 37 C.F.R. § 1.98(a), copies of the references listed on pages 1-18 of the Form PTO-1449 are enclosed. If it is determined that any of the listed references are not presently enclosed, the Examiner is requested to contact the undersigned so that a copy can be forwarded. It is respectfully requested that the references cited in the accompanying Form PTO-1449 be considered and made of record.

The Examiner's attention is respectfully directed to the following references, which are cited in the specification of the present application and are listed on the attached Form-PTO 1449:

EP(A2) 0240906- corresponding U.S. patent listed as reference DD

EP(A2) 0358105- corresponding U.S. patent listed as reference BG

EP(A2) 0118240-listed as reference RH

EP(A1) 0580860-listed as reference BN

The Examiner's attention is also respectfully directed to the following references, which were cited in the Preliminary Examination Report of the present application:

WO 92/15285-listed as reference RI
WO 98/10762-listed as reference RJ
U.S. Patent No. 4,612,009-listed as reference RD

Applicants respectfully advise the Examiner of the following U.S. Patents and co-pending U.S. Patent Applications which are commonly assigned to the owners of the instant application:

U.S. Application Serial No. 10/690,389, filed October 21, 2003, entitled, "Melt-Extruded Orally Administrable Opioid formulations", pending, which is a continuation of U.S. Application Serial No. 09/777,616, filed February 6, 2001, entitled, "Melt-Extruded Orally Administrable Opioid formulations", pending, which is a continuation application of U.S. Application Serial No. 09/360,056, filed July 23, 1999, entitled "Melt-Extruded Orally Administrable Opioid formulations", now U.S. Patent No. 6,261,599, issued July 17, 2001, which is a continuation application of U.S. Application Serial No. 08/833,948, filed April 10, 1997, now U.S. Patent No. 5,958,452, issued September 28, 1999, which is a continuation-in-part of PCT/US95/14745, filed November 3, 1995, which is a continuation-in-part of U.S. Application Serial No. 08/334,209, filed November 4, 1994, now U.S. Patent No. 5,965,161;

U.S. Application Serial No. 10/038,867, filed January 2, 2003, entitled, "Melt-Extrusion Multiparticulates", pending, which is a continuation application of 09/358,828, filed July 22, 1999, entitled, "Melt-Extrusion Multiparticulates", now U.S. Patent No. 6,335,033, issued January 1, 2002, which is a continuation application of U.S. Application Serial No. 08/334,209, filed November 4, 1994, entitled, "Extruded Multiparticulates", now U.S. Patent No. 5,965,161, issued October 12, 1999.

Pursuant to 37 C.F.R. § 1.98 (a)(2)(iii), the Examiner's attention is directed to **Exhibit A**, attached herewith, which contains the following:

(i) the claims of pending applications serial nos. 10/690,389 and 09/777,616, which have

the same specification as U.S. Patent No. 5,958,452, listed as reference RB on the attached Form

PTO 1449.

(ii) the claims of pending application serial no. 10/038,867, which has the same

specification as U.S. Patent No. 6,335,033, listed as reference RC on the attached

Form PTO 1449.

The present Information Disclosure Statement is filed under 37 C.F.R. §1.97(c), after the

mailing of a first Office Action on the merits. Accordingly, a check in the amount of \$180.00 is

enclosed. If it is determined that any additional fee is due, the Examiner is authorized to charge

said fee to Attorney Deposit Account No. 50-0552.

It is respectfully requested that the reference cited on the accompanying Form PTO-1449

be considered and made of record.

Respectfully submitted,

DAVIDSØN, DAVIDSON & KAPPEL, LLC

D.,,

Robert J. Paradiso

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FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE ATTY. DOCKET NO .: SERIAL NO.: 09/980,727 PATENT AND TRADEMARK OFFICE 228.1010 (REV. 7-80) CO 1.0 . . . APPLICANT(S): LIST OF PRIOR ART CITED BY APPLICANT Hubert REIN, et al. (Use several sheets if necessary) FILING DATE: GROUP: 1615 October 19, 2001 **U.S. PATENT DOCUMENTS DOCUMENT NUMBER** SUBCLASS FILING DATE *EXAMINER DATE NAME CLASS INITIAL IF APPROPRIATE 4 2 7 01/02/79 25 11/03/67 AA 3 Blichare et al. 264 5 2 3 AB 4 3 3 08/06/85 Ikegami et al. 427 04/19/84 7 6 4 3 08/16/88 435 AC 4 Ą Keith et al. 424 02/10/86 4 8 2 8 AC 8 3 6 05/09/89 Elger et al. 424 419 05/19/87 4 2 ΑE 11/21/89 Jang 424 468 11/24/87 AF 4 8 9 4 3 11/14/89 424 470 3 0 Rhodes 02/09/87 9 4 2 AG 4 8 3 01/16/90 Sharma et al. 424 440 07/26/88 4 9 9 4 2 AH 02/19/91 Dietz et al. 264 328.16 02/03/89 AL 5 0 3 06/11/91 0 8 9 Sakamoto et al. 424 502 07/13/89 AJ • 0 5 5 3 0 7 10/08/91 693 12/28/89 Tsuru et al. 424 A۳ 5 07/28/92 Paradissis et al. 424 480 01/24/90 FOREIGN PATENT DOCUMENTS DOCUMENT NUMBER DATE COUNTRY CLASS SUBCLASS TRANSLATION NO AL WO 94 0 Ą 5 6 8 04/28/94 PCT A61K 9/26 **Abstract** WO 2 9 AM 94 3 6 8 10/27/94 PCT A61K 9/14 ΑN WO 93 2 4 7 0 12/09/93 PCT A61K 9/20 Abstract ΑŒ wo 93 0 2 8 04/29/93 5 9 PCT A61K 9/16 ΑP 0 θ 1 EPO(A2) 6 0 0 04/22/92 A61L 15/28 OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.) ΑQ Nicolas Follonier 1, Eric Doelker and Ewart T. Cole, Evaluation of Hot-Melt Extrusion as a New Technique for the Production of Polymer-Based Pellets for Sustained Release Capsules containing high loadings of freely soluble drugs, Drug Development and Industrial Pharmacy, 20(8), 1323-1339 (1994) Nicolas Follonier¹, Eric Doelker¹ and Ewart T. Cole², <u>Hot-Melt Extruded Pellets for the Sustained Release of Highly Dosed</u> AR Freely Solluble Drugs, Proceed. Intern. Symp. COntrol. Rel. Bioact. Mater., 18(1991), pages 578-579 Twin Screw Extrusion in the Production of Novel Dosage Forms, Pharmaceutical Manufacturing Review (June 1994) AS **EXAMINER** DATE CONSIDERED *EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

| FORM PTO-1449 (REV. 7-80) | | | | | | | | | T OF COMMERCE ADEMARK OFFICE | ATTY. DOCKET NO.: 228.1010 | | SERIAL NO.: 09/ | 980, 727 | |
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| . <u> </u> | BA | 5 | 2 | 7 | 3 | 7 | 5 | 8 | 12/28/93 | Royce | 424 | 465 | 04/13/92 | |
| | BB | 5 | 3 | 8 | 3 | 5 | 3 | 5 | 01/10/95 | Geyer et al. | 424 | 484 | 11/25/92 | |
| | BC | 5 | 2 | 8 | 2 | 1 | 2 | 8 | 04/13/93 | Morella et al. | 424 | 465 | 08/24/90 | |
| | BD | Re. | | 1 | 3 | 0 | 3 | 3 | 10/17/89 | Schiraldi et al. | 424 | 676 | 11/16/88 | |
| | BE | 5 | 3 | 9 | 6 | 6 | 3 | 9 | 10/18/94 | Raman et al. | 424 | 484 | 07/13/93 | |
| | BI | 5 | 1 | 8 | 3 | 6 | 3 | 9 | 02/02/93 | Carr et al. | 427 | 213.31 | 06/25/90 | |
| <u>"</u> . | BG | 5 | 0 | 7 | 3 | 3 | 7 | 9 | 12/17/91 | Klimesch et al. | 424 | 467 | 08/25/89 | |
| | ВН | 4 | 9 | 5 | 7 | 6 | 3_ | 1 | 09/18/90 | Klimesch et al. | 264 | 211.23 | 04/03/89 | |
| | BI | 5 | 2 | 8 | 3 | 0 | 6 | 5 | 2/1/94 | Doyon, et al. | 424 | 467 | 3/23/92 | |
| | ВЈ | 4 | 8 | 0 | 6 | 3 | 3 | 7 | 2/21/89 | Snipes, et al. | 71 | 65 | 10/14/86 | |
| | ВК | 5 | 2 | 9 | 0 | 5 | 6 | 0 | 3/1/94 | Autant, et al. | 424 | 438 | 6/21/91 | |
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| | ВМ | 0 | 5 | 8 | 0 | 3 | 6 | 0 | 02/02/94 | EPO (A1) | A61K | 9/14 | | |
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| | BN | | | | t al., "F | lot-Melt | Extrude | ed Pellet | | Release Of Highly Dose | | Drugs", | | |
| | во | | | | | | nd Use ry 1973 | | oratory Extruder for | Pharmaceutical Granula | itions, Journal o | f Pharm. | · · · · · · · · · · · · · · · · · · · | |
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| | CA | 5 | 0 | 4 | 9 | 3 | 5 | 4 | 9/17/91 | Howard, et al. | 424 | 490 | 3/15/89 | |
| | СВ | 4 | 3 | | 1 | 5 | 9 | 5 | 8/29/89 | Oshlack | 424 | 468 | 7/18/86 | |
| | cc | 4 | 3 | 1 | 8 | 4 | 5 | 5 | 4/4/89 | Hall, et al. | 264 | 39 | 10/27/86 | |
| | CŒ | 4 | 7 | 2 | 6 | 3 | 3 | 4 | 1/19/88 | DiLuccio, et al. | 424 | 78 | 8/21/86 | |
| | CE | 4 | 3 | 7 | 4 | 4 | 8 | 2 | 2/15/83 | Hochschild | 264 | 129 | 8/18/91 | |
| | CF | 3 | 8 | 8 | 0 | 9 | 9 | 1 | 04/29/75 | Yolles | 424 | 22 | | |
| | CG | 4 | 2 | 6 | 5 | 8 | 7 | 5 | 05/05/81 | Byrne, et al. | 424 | 19 | | |
| | CI | 4 | 2 | 9 | 7 | 3 | 5 | 5 | 09/29/81 | Byrne, et al. | 424 | 19 | | |
| | CI | 4 | 3 | 4 | 4 | 4 | 3 | 1 | 08/17/82 | Yolles | 128 | 260 | | , |
| | CJ | 4 | 3 | 4 | 6 | 7 | 3 | 9 | 08/31/82 | Schmitt | 128 | 260 | | |
| | CK | 4 | 4 | 0 | 6 | Ą | 5 | 9 | 09/27/83 | Byrne, et al. | 424 | 80 | | |
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| | DA | 3 | 6 | 2 | 1 | 1 | 1 | 3 | 11/04/86 | Watenabe | 524 | 451 | | |
| | DB | 3 | 8 | 4 | S | 8 | 4 | 2 | 03/10/87 | Davis, et al. | 424 | 438 | | |
| | DC | 4 | 6 | 6 | 1 | 6 | 6 | 8 | 01/31/89 | Goertz, et al. | 424 | 465 | | |
| | DD | 4 | 8 | 6 | 6 | 5 | 3 | 5 | 11/14/89 | Klimesch, et al. | 264 | 141 | | |
| | DE | 0 | 9 | 7 | G | 6 | 7 | 5 | 11/13/90 | Oshlack | 424 | 451 | | |
| | DE | 3 | 9 | 8 | 2 | 1 | 0_ | 8 | 02/12/91 | Koepff,et al. | 106 | 1258 | | |
| | DG | 5 | 1 | 8 | 2 | 8 | 6 | 8 | 04/07/92 | Eichel, et al. | 424 | 490 | | |
| | DH | 5 | 9 | 5 | 0 | 5 | 8 | 2 | 09/27/94 | McClelland, et al. | 424 | 501 | | |
| | DC | 5 | 4 | 5 | 6 | 9 | 2 | 3 | 10/10/95 | Nakamichi, et al. | 424 | 489 | | |
| | DJ | 4 | 1 | 7 | 3 | 4 | 1 | 1 | 11/6/79 | Kruder | 366 | 89 | 6/20/78 | |
| | DK | 4 | 2 | 9 | 0 | 6 | 8 | 1 | 10/28/80 | Sair et al. | 424 | 22 | 5/30/78 | |
| | DL | 4 | 7 | 7 | 8 | 6 | 7 | 0 | 10/18/88 | Yang et al. | 424 | 79 | 12/20/85 | |
| | DM | 4 | 8 | 4 | 2 | 7 | 6 | 1 | 6/27/89 | Rutherford | 252 | 90 | 3/23/88 | |
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| | EA | 4 | 8 | 7 | 9 | 4 | 0 | 8 | 11/7/89 | Yang et al. | 424 | 440 | 10/14/88 | |
| | EB | 4 | a | 8 | 2 | 1 | 5 | 1 | 11/21/89 | Yang et al. | 424 | 440 | 10/14/88 | |
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| | EE | 4 | 8 | 8 | 2 | 1 | 5 | 5 | 11/21/89 | Yang et al. | 424 | 440 | 10/14/88 | |
| | EF | 4 | 8 | 8 | 2 | 1 | 5 | 6 | 11/21/89 | Yang et al. | 424 | 440 | 10/14/88 | |
| | EG | 5 | 3 | _5 | 4 | 8_ | 5 | 6 | 10/11/94 | Kawashima et al. | 536 | 127 | 05/23/91 | |
| | ΕI | 4 | 8 | 8 | 7 | 1 | 5 | 1_ | 11/21/89 | Yang et al. | 424 | 440 | 10/14/88 | |
| | ΕI | 4 | 8 | 8 | 2 | 1 | 5 | 9 | 11/21/89 | Yang et al. | 424 | 440 | 10/14/88 | |
| | EJ | 4 | 9 | 5 | 9 | 2 | g g | 8 | 9/25/90 | Chakrabarti et al. | 424 | 78 | 10/28/88 | |
| ··· | EK | 5 | 9 | 3 | 5 | 5 | 0 | 9 | 7/30/91 | Kruder | 366 | 89 | 8/13/90 | |
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| | ES | Seki | guchi, | et al., ' | 'Studie | s on A | bsorpti | on of E | utectic Mixture | ", Chem. Pharm. B | ull., Vol. 9 (19 | 961), pp. 866-872 | | |
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| FI FI FI FI | D E | 5 | 2 | | 0 | 4 | 0 | 9 | 8/31/93 | Fujimoto et al. | 425 | 310 | 7/27/92 | |
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| FI | | 5 | 4 | 7 | 6 | 5 | 2 | 8 | 12/19/95 | Trimm et al. | 71 | 21 | 12/20/93 | |
| F | ·G | 5 | 5 | 1 | 0_ | 1 | 1 | 4 | 4/23/96 | Borella et al. | 424 | 452 | 5/2/94 | |
| | н | 5 | 5 | 1 | 6 | 2 | 0 | 5 | 5/14/96 | Oda et al. | 366 | 75 | 1/12/95 | |
| F. | -1 | 5 | 5 | 5 | 2 | 1 | 5 | 9 | 9/3/96 | Mueller et al. | 424 | 464 | 9/23/93 | |
| | J | 5 | 5 | 6 | 7 | 4 | 3 | 9 | 10/22/96 | Myers et al. | 424 | 486 | 11/4/94 | |
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| | IC | 4 | 3 | 8 | 0 | 5 | 3 | 4 | 4/19/83 | Fukui, et al. | 264 | 38 | | |
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| | JG | 4 | 9 | 6 | 7 | 4 | е | 6 | 11/6/90 | Doelling | 34 | 1 | | |
| | JO. | 4 | | 7 | 0 | 0 | 7 | 5 | 11/13/90 | Oshlack | 424 | 451 | | |
| | JF | 4 | | 8 | 7 | 1 | 3 | | 1/22/91 | Kreek et al. | 514 | | | |
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| | LR | | | | | | | | Matrix Pellets 67-1887 (1993) | Prepared by Melt Pelleti | zation I. Proc | ess Variables", Dr | ug Developme | nt and |
| | LS | Thor Bind | msen, lers", C | L. Juul Orug De | et al., | "Prolo | nged F | Release | Matrix Pellets | Prepared by Melt Pellet 20, No. 7, pp. 1179-119 | ization II. Hyd | drophobic Substan | ces as Meltabl | е |
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